PerkinElmer
For the Better

APR 16 2009

510(k) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR § 807.92.

The Assigned 510(k) Number is: K081922

Submitter:	Wallac Oy Mustionkatu 6 20750 Turku, Finland Telephone: +358 2 2678111 Fax: +358 2 2678357
Contact Person:	Katriina Suonpää Regulatory Affairs Manager katriina.suonpaa@perkinelmer.com
Date of Summary Prepared:	April 07, 2009
Device Name:	AutoDELFIA® Neonatal 17α-OH-progesterone kit
Classification Name:	Radioimmunoassay, 17-Hydroxyprogesterone Class I per 21 CFR § 862.1395
Product Code:	JLX
Predicate Device:	AutoDELFIA® Neonatal 17α-OH-progesterone kit, 510(k) Number K042425
Device Description:	The AutoDELFIA Neonatal 17α-OH-progesterone (17-OHP) assay is a solid phase, time-resolved fluoroimmunoassay based on the competitive reaction between europium-labeled 17-OHP and sample 17-OHP for a limited amount of binding sites on 17-OHP specific polyclonal antibodies (derived from rabbit). Danazol facilitates the release of 17-OHP from the binding proteins. A second antibody, directed against rabbit IgG, is coated to the solid phase, giving convenient separation of the antibody-bound and free antigen.

PerkinElmer
For the Better

Enhancement Solution dissociates europium ions from the labeled antigen into solution where they form highly fluorescent chelates with components of the Enhancement Solution. The fluorescence in each well is then measured. The fluorescence of each sample is inversely proportional to the concentration of 17-OHP in the sample.

Intended Use:

The AutoDELFIA Neonatal 17α-OH-progesterone kit is intended for the quantitative determination of human 17α-OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the 1235 AutoDELFIA® automatic immunoassay system.

Substantial Equivalence:

The AutoDELFIA Neonatal 17α-OH-progesterone kit (B024) is substantially equivalent to our currently marketed AutoDELFIA Neonatal 17α-OH-progesterone kit (B015) (K042425). The primary difference is a new antiserum in B024. The new antiserum has less cross-reactivity with the physiologically important steroids in neonates, making it more specific for measuring 17α-OH-progesterone. There are the following similarities and differences between the two kits:

PerkinElmer
For the Better

Table 1. Characteristics of the two kits.

Characteristic	**Proposed Device AutoDELFIA Neonatal 17α-OH-progesterone kit B024**	**Predicate Device AutoDELFIA Neonatal 17α-OH-progesterone kit B015**
Similarities		
Intended User	Adequately trained laboratory personnel in laboratories performing newborn screening	Adequately trained laboratory personnel in laboratories performing newborn screening
Intended Use	Quantitative determination of 17α-OH-progesterone in blood specimens dried on filter paper	Quantitative determination of 17α-OH-progesterone in blood specimens dried on filter paper
Indication for Use	An aid in screening newborns for congenital adrenal hyperplasia	An aid in screening newborns for congenital adrenal hyperplasia
Chemical Principle	Competitive reaction between europium labeled 17-OHP and sample 17-OHP for a limited number of binding sites on 17-OHP specific polyclonal antibodies derived from rabbit	Competitive reaction between europium labeled 17-OHP and sample 17-OHP for a limited number of binding sites on 17-OHP specific polyclonal antibodies derived from rabbit
Assay Principle	Time-resolved fluoroimmunoassay	Time-resolved fluoroimmunoassay
Instrument	1235 AutoDELFIA automatic immunoassay system	1235 AutoDELFIA automatic immunoassay system
Detection principle	Time-resolved fluorescence	Time-resolved fluorescence
Specimen	Filter paper disks with a diameter of approximately 3.2 mm (1/8 inch)	Filter paper disks with a diameter of approximately 3.2 mm (1/8 inch)
Calibrator and Control Matrix	Human blood with a hematocrit of 50-55% and spotted onto filter paper cassettes (Whatman Grade 903)	Human blood with a hematocrit of 50-55% and spotted onto filter paper cassettes (Whatman Grade 903)
Calibration	Calibrated using gravimetric methods	Calibrated using gravimetric methods
Controls	3 levels (approx. values 17, 45 and 100 ng/mL serum)	3 levels (approx. values 17, 45 and 100 ng/mL serum)
Assay Buffer	17-OHP Assay Buffer, ready for use	17-OHP Assay Buffer, ready for use
Coated Plates	Anti-rabbit IgG Microtitration Strips, 8 x 12 wells coated with anti-rabbit IgG (raised in goat)	Anti-rabbit IgG Microtitration Strips, 8 x 12 wells coated with anti-rabbit IgG (raised in goat)

PerkinElmer
For the Better

Characteristic, continued	**Proposed Device AutoDELFIA Neonatal 17α-OH-progesterone kit B024**	**Predicate Device AutoDELFIA Neonatal 17α-OH-progesterone kit B015**
	Differences	
Antibodies	Rabbit polyclonal antibodies	Different rabbit polyclonal antibodies
Antibody Cross-Reactions in the Assay	17α-OH pregnenolone sulfate 0.78 % 11-Deoxycortisol 0.62 % 17α-OH pregnenolone 0.83 % Progesterone 0.37 %	17α-OH pregnenolone sulfate 2.0 % 11-Deoxycortisol 1.82 % 17α-OH pregnenolone 1.20 % Progesterone 0.47 %
Tracer	17-OHP-Eu tracer stock solution, approximate concentration of 40 nmol/L, lyophilized	17-OHP-Eu tracer stock solution, approximate concentration of 250 nmol/L, lyophilized
Calibrators	6 levels (approx. values 0, 4, 10, 25, 75, and 220 ng/mL serum)	6 levels (approx. values 0, 10, 25, 50, 100 and 250 ng/mL serum)
Analytical Sensitivity / Limit of Blank, Limit of Detection, Limit of Quantitation	Limit of Blank 0.37 ng/mL serum Limit of Detection 0.84 ng/mL serum Limit of Quantitation 1.4 ng/mL serum	Analytical Sensitivity (Limit of Blank) 1.3 ng/mL serum
Precision (Total Variation using a full calibration curve on each plate)	2.12 ng/mL serum CV% 13.0 4.69 ng/mL serum CV% 9.8 7.52 ng/mL serum CV% 14.8 27.0 ng/mL serum CV% 8.3 54.4 ng/mL serum CV% 9.2 109 ng/mL serum CV% 10.8 182 ng/mL serum CV% 9.1	25.9 ng/mL serum CV% 13.2 53.0 ng/mL serum CV% 10.8 114 ng/mL serum CV% 10.9
Precision (Total Variation using one calibration curve for every batch of 4 plates)	2.25 ng/mL serum CV% 14.0 4.89 ng/mL serum CV% 12.0 7.79 ng/mL serum CV% 15.8 27.7 ng/mL serum CV% 9.7 55.7 ng/mL serum CV% 10.5 113 ng/mL serum CV% 12.7 188 ng/mL serum CV% 11.3	25.8 ng/mL serum CV% 14.0 52.9 ng/mL serum CV% 12.4 115 ng/mL serum CV% 11.8
Median Values in Newborn Screening (Study 1)	< 1250 g 20.9 ng/mL serum 1250-2249 g 9.7 ng/mL serum ≥ 2250 g 6.7 ng/mL serum	< 1250 g 35.6 ng/mL serum 1250-2249 g 20.0 ng/mL serum ≥ 2250 g 14.1 ng/mL serum
Median Values in Newborn Screening (Study 2)	< 1250 g 13.3 ng/mL serum 1250-2249 g 12.1 ng/mL serum ≥ 2250 g 7.1 ng/mL serum	< 1250 g 30.2 ng/mL serum 1250-2249 g 23.4 ng/mL serum ≥2250 g 13.7 ng/mL serum

PerkinElmer
For the Better

Screening Efficacy:

The proposed kit and the predicate device were compared in two newborn screening laboratories using retrospective specimens and excess samples. A number of known CAH cases were included. The results categorizing the number of evaluation samples according to screening outcome are shown in Tables 2-7 (Study 1) and in Tables 8-13 (Study 2).

Study 1, Tables 2 - 7:
In total, 17 confirmed CAH case samples were available for the study. All of them were retrospective samples.

Table 2. Screening results and true diagnosis in the < 1250 g weight category, 90th percentile.

New kit B024 Cut-off 56.7 ng/mL	Old kit B015 Cut-off 135 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	31	1	30
+	-	7	0	7
-	+	7	0	7
-	-	319	1*	318
Total		364	2	362

Table 3. Screening results and true diagnosis in the < 1250 g weight category, 95th percentile.

New kit B024 Cut-off 73.6 ng/mL	Old kit B015 Cut-off 178 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	13	1	12
+	-	7	0	7
-	+	7	0	7
-	-	337	1*	336
Total		364	2	362

* In this case, the mother had CAH. Treatment for CAH includes lifetime daily medication, prednisone or dexamethasone. Because the specimen was taken during the first day of life, the mother's treatment would have impacted the 17-OHP test result of the infant.

PerkinElmer
For the Better

Table 4. Screening results and true diagnosis in the 1250-2249g weight category, 90th percentile.

New kit B024 Cut-off 33.5 ng/mL	Old kit B015 Cut-off 76.9 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	38	1	37
+	-	16	1	15
-	+	13	0	13
-	-	433	0	433
Total		500	2	498

Table 5. Screening results and true diagnosis in the 1250 - 2249g weight category, 95th percentile.

New kit B024 Cut-off 40.8 ng/mL	Old kit B015 Cut-off 98.4 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	17	0	17
+	-	10	2	8
-	+	8	0	8
-	-	465	0	465
Total		500	2	498

Table 6. Screening results and true diagnosis in the ≥ 2250 g weight category, 90th percentile.

New kit B024 Cut-off 14.3 ng/mL	Old kit B015 Cut-off 31.5 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	119	13	106
+	-	28	0	28
-	+	26	0	26
-	-	1155	0	1155
Total		1328	13	1315

PerkinElmer
For the Better

Table 7. Screening results and true diagnosis in the ≥ 2250 g weight category, 95th percentile.

New kit B024 Cut-off 20.9 ng/mL	Old kit B015 Cut-off 49.0 ng/mL	Total subjects	Diagnosed CAH	No diagnosed CAH
+	+	60	11	49
+	-	19	2	17
-	+	18	0	18
-	-	1231	0	1231
Total		1328	13	1315

Study 2, Tables 8 - 13:
Confirmed CAH case samples were available only in the ≥ 2250g birth weight category, in total 13 cases. All of them were retrospective samples.

Table 8. Screening results and true diagnosis in the < 1250 g weight category, 90th percentile.

New kit B024 Cut-off 59.5 ng/mL	Old kit B015 Cut-off 125 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	15	0	15
+	-	2	0	2
-	+	2	0	2
-	-	149	0	149
Total		168	0	168

Table 9. Screening results and true diagnosis in the < 1250 g weight category, 95th percentile.

New kit B024 Cut-off 95.0 ng/mL	Old kit B015 Cut-off 202 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	5	0	5
+	-	4	0	4
-	+	4	0	4
-	-	155	0	155
Total		168	0	168

PerkinElmer
For the Better

Table 10. Screening results and true diagnosis in the 1250 - 2249g weight category, 90th percentile.

New kit B024 Cut-off 54.3 ng/mL	Old kit B015 Cut-off 137 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	30	0	30
+	-	8	0	8
-	+	8	0	8
-	-	326	0	326
Total		372	0	372

Table 11. Screening results and true diagnosis in the 1250 - 2249g weight category, 95th percentile.

New kit B024 Cut-off 68.6 ng/mL	Old kit B015 Cut-off 167 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	11	0	11
+	-	8	0	8
-	+	8	0	8
-	-	345	0	345
Total		372	0	372

Table 12. Screening results and true diagnosis in the ≥ 2250 g weight category, 90th percentile.

New kit B024 Cut-off 16.1 ng/mL	Old kit B015 Cut-off 32.9 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	121	13	108
+	-	21	0	21
-	+	21	0	21
-	-	1136	0	1136
Total		1299	13	1286

PerkinElmer
For the Better

Table 13. Screening results and true diagnosis in the ≥ 2250 g weight category, 95th percentile.

New kit B024 Cut-off 28.3 ng/mL	Old kit B015 Cut-off 66.5 ng/mL	Total Subjects	Diagnosed CAH	No diagnosed CAH
+	+	68	12	56
+	-	9	0	9
-	+	10	0	10
-	-	1212	1*	1211
Total		1299	13	1286

* Using percentiles higher than the 90th percentile as the assay's cut-off resulted in one false negative result out of the 13 clinically confirmed CAH samples assayed. Laboratories should take this into consideration when setting their screening cut-offs.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Wallac Oy
c/o Katriina Suonpää
Regulatory Affairs Manager
Mustionkatu 6
20750 Turku, Finland

APR 1 6 2009

Re: k081922
Trade/Device Name: AutoDELFIA Neonatal 17α-OH-progesterone kit
Regulation Number: 21 CFR 862.1395
Regulation Name: Radioimmunoassay, 17-Hydroxyprogesterone
Regulatory Class: Class I, meets limitations of exemptions under 21 CFR § 862.9 (c)(2)
Product Code: JLX
Dated: March 27, 2009
Received: April 2, 2009

Dear Katriina Suonpää:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 594-3084. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Courtney C. Harper, Ph.D.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Indication for Use

510(k) Number (if known): K081922

Device Name: AutoDELFIA® Neonatal 17α-OH-progesterone kit

Indication For Use: The AutoDELFIA® Neonatal 17α-OH-progesterone kit is intended for the quantitative determination of human 17α-OH-progesterone in blood specimens dried on filter paper as an aid in screening newborns for congenital adrenal hyperplasia (CAH) using the 1235 AutoDELFIA® automatic immunoassay system.

Prescription Use X (21 CFR Part 801 Subpart D) And/Or Over the Counter Use ____. (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Carol C. Benson

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K081922